

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-2001V

UNPUBLISHED

LESLIE KRAUS,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

Filed: September 2, 2021

Chief Special Master Corcoran

Special Processing Unit (SPU);
Entitlement; Ruling on the Record;
Decision Without a Hearing;
Causation-In-Fact; Influenza (Flu)
Vaccine; Shoulder Injury Related to
Vaccine Administration (SIRVA)

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Petitioner.*

Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On December 21, 2017, Leslie Kraus filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa–10, *et seq.*² (the “Vaccine Act” or “Program”), alleging that she suffered from a shoulder injury related to vaccine administration (“SIRVA”) after receiving an influenza (“flu”) vaccination on September 26, 2016. Petition at 1 (Preamble). The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed herein, I find that Petitioner is entitled to compensation.

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). I intend to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Ms. Kraus filed her petition on December 21, 2017. (ECF No. 1). She filed the relevant medical records and a Statement of Completion over the next four months. (ECF Nos. 6-7, 9-10, 12-13). By September 2018, Respondent had reviewed all the records in the case and filed a status report stating that he was amenable to settlement discussions. (ECF No. 19). Settlement discussions broke down in the summer of 2019, however, and a deadline was set for the filing of Respondent's Rule 4(c) report to identify the areas of disagreement. (ECF Nos. 35, 37).

Respondent filed his Rule 4(c) Report on August 29, 2019, in which he argued that "[t]he current record does not establish by preponderant evidence that petitioner developed SIRVA as a result of her alleged September 26, 2016 flu vaccination, as there are insufficient records substantiating that the onset of petitioner's right shoulder pain began within forty-eight hours of vaccination." (ECF No. 40). The parties agreed to brief the case (including any disputed factual issues) and requested a ruling on the record. The parties have completed briefing, and this case is now ripe for adjudication. After a review of the entire record, I find that Petitioner is entitled to compensation.

II. Factual History

On September 26, 2016, Ms. Kraus (a 54-year-old disability claims adjuster at Prudential Insurance Company) received a flu vaccine in her right deltoid at the office of her primary care provider, Dr. Victoria Borgia, located in Bensalem, Pennsylvania. Exhibit ("Ex.") 1 at 1; Ex. 2 at 46. Although there is a mention of a fall in her medical notes that may have impacted her right shoulder, that fall took place 15 years prior. Ex. 4 at 21. There is no other documented history of any right shoulder injuries in the three years prior to September 26, 2016.³ See *generally* Exs. 4 at 19, Ex. 23 at 1, ¶2.

In her affidavit, Ms. Kraus describes the circumstances of the vaccination, stating:

[a]n assistant of Dr. Borgia's gave me the shot in my right shoulder. Within two days, my arm was sore with an inflammatory type pain. I did not think anything of it because it had only been a couple of days after the shot and I felt that type of pain could happen. I went through my daily life but noticed right away that the soreness was not going away.

Ex. 9 at ¶1.

³ Ms. Kraus's medical history included allergic rhinitis, arthritis, backache, bronchitis, GERD, "neck burn," sleep apnea, tendinitis of the ankle), Ex. 4 at 10, 35-41 (clogged right ear), 42-50 (coccyx pain and low back pain); Ex. 6 at 9-15, 23 (ankle contusion).

On October 17, 2016 (three weeks after her vaccination), Ms. Kraus presented to Dr. Bindu Mathew as a new patient for left foot and ankle pain that had been present for a number of months. Ex. 4 at 24-26. Dr. Mathew noted joint pain and back pain under “Review of Systems,” but did not record any shoulder complaints. *Id.* at 25.

Approximately two months later, on December 20, 2016, Ms. Kraus presented to Dr. Borgia with complaints of right shoulder pain. Ex. 4 at 19-21. The note from this visit states “right shoulder pain x years but in the past month its [sic] become more painful.” *Id.* at 19. Under history of present illness, Dr. Borgia noted, “R[ight] shoulder pain intermittent x years, increasing in frequency,” no decreased range of motion, and referenced a fall Ms. Kraus had 15 years prior. *Id.* No abnormal findings are noted on the physical exam. *Id.* at 21. The assessment was tendinopathy, and Dr. Borgia prescribed Naproxen and referred Ms. Kraus to physical therapy (“PT”). *Id.*

Approximately one month later, on January 16, 2017, Dr. Borgia amended this record to include:

Addendum ... amended 1/16/17: per p[atien]t report, had flu shot in affected shoulder and on exam, did have area of thickened tissue at site on deltoid. However, exam consistent with a tendonitis with ratiation [sic]. THIS DOCUMENT HAS BEEN AMENDED.

Ex. 4 at 19. To explain this addendum, Ms. Kraus in her affidavit stated:

On December 20, 2016, I went to see Dr. Borgia and I expressed that I couldn't understand why I was having so much pain in my shoulder joint since I had not injured myself. I indicated that the only thing that ever happened to me was around 12-15 years ago, I fell on my neighbor's driveway. I put ice on my right hip and right arm, and called it a day. The pain I experienced as a result of that fall was not nearly as painful as the pain I was having presently...

I later learned that Dr Borgia had failed to note in the records of my December 20, 2016, office visit where I stated that the vaccine injection site was still painful. She also embellished what I stated about my reported fall years ago. I asked her to correct my office visit note and she, once again, put statements that did not correlate with what I reported and what we discussed... On my next office visit, she apologized for the incorrect information noted in my record of December 20, 2016. She stated her medical assistant put the inaccurate information in my office visit note and

she often doesn't check the notes. She further advised that she would correct that information in the office note for January 20, 2017. She made note in the January 20, 2017 office visit note that the prior office visit note had erroneous information.

Ex. 9 at 1-2, ¶¶4-5.

Ms. Kraus returned to Dr. Borgia on January 20, 2017, about four days after Dr. Borgia amended the December 20, 2016 visit note. Ex. 4 at 15-18. Ms. Kraus reported "she is here because in September she got a flu shot in her right arm and ever since then she has had pain in her upper arm that goes up to her shoulder." *Id.* at 15. She also stated that she had "no issue until 2 day[s] after." *Id.* Ms. Kraus explained that she "felt some soreness which she attributed to customary soreness [that] did not resolve." *Id.* She had full range of motion, but the pain was worse when she lifted her arm to use her computer and when drying her hair. *Id.* Dr. Borgia noted that at the prior visit she had "erroneously attributed this new pain to exacerbation of an old injury" to the same shoulder after a fall many years ago. *Id.* Dr. Borgia prescribed a course of oral steroids and ordered an MRI. *Id.* at 13-18; Ex. 5 at 5; Ex. 6 at 16-17.

Ms. Kraus underwent the MRI of her right shoulder on February 17, 2017. Ex. 2 at 23; Ex. 4 at 13-14. The impression was a "[t]iny high-grade insertional infraspinatus tendon tear. 2. No evidence of soft tissue collection or signs of septic arthritis." *Id.* The indication on the MRI report stated, "Pain after a flu shot." *Id.*

Ms. Kraus met with Dr. Borgia on February 20, 2017, to review the results of her MRI. Dr. Borgia explained that the MRI showed a "tiny tear" of the infraspinatus tendon. Ex. 4 at 10, 13. Dr. Borgia also noted that she "found other examples of [rotator cuff] problems after flu [immunization]," and she planned to report Ms. Kraus's reaction to VAERS. *Id.* at 10, 12. During this visit, Ms. Kraus received a steroid injection to her right shoulder to treat the pain and inflammation. *Id.* at 10-12. She was also referred to PT. *Id.*

Ms. Kraus began physical therapy for her right shoulder on March 8, 2017. Ex. 2 at 8-15. She described her pain as a 5, on a 0 to 10 scale. Ex. 4 at 7. Ms. Kraus was discharged after seven sessions. Ex. 2 at 8-15. Then, on April 3, 2017, Ms. Kraus presented to Julie Todd, D.O., at Bucks Family Medicine for a "general physical exam." Ex. 5 at 3. The history of present illness section of the note states "[c]omplaints of right shoulder pain since 9/26/17⁴ after receiving flu shot in her right arm." *Id.* The "Nurse Note" on the same page states "P[atien]t has r[igh]t delt/shoulder pain since receiving flu shot

⁴ This date is a typo. There is no dispute that Ms. Kraus received the flu vaccine on September 26, 2016. See Ex. 1 at 1.

on 9-26-16. P[atien]t states pain started 2 days after injection.” *Id.* Ms. Kraus reported that her symptoms had not improved with PT and a steroid injection. *Id.* Dr. Todd encouraged her to continue with PT and referred her to an orthopedist. *Id.*

A week later, on April 10, 2017, Ms. Kraus presented to Dr. Steven A. Caruso at Trenton Orthopaedic Group. Ex. 6 at 4-8. She had seen another orthopedist in this practice group in the past for a right ankle problem. *Id.* at 9-11, 14-15, 19, 22-23. Under History of Present Illness, Dr. Caruso notes

Leslie is a pleasant 55-year-old left-hand dominant female who presents today with right shoulder pain. She has this pain since September. She is [sic] obtained a flu shot and she states that she has had this pain since this flu shot. . .

Id. On exam, Ms. Kraus exhibited pain to palpitation of her right shoulder and pain at the end of full range of motion. *Id.* at 4-8. When Ms. Kraus inquired, “whether or not the flu shot [was] the reason for her pain,” Dr. Caruso stated that he could not confirm it. *Id.* at 7. He continued, “I believe it is possible and the axillary nerve does cross the anterior and lateral shoulder and I believe it depends on where the injection is,” noting further, however, “I have never seen this or what this does in my practice before.” *Id.* The assessment was right shoulder pain and “partial thickness rotator cuff tear.” *Id.* Dr. Caruso echoed Dr. Todd’s recommendation that Ms. Kraus continue with PT. *Id.* That same day she began physical therapy at NovaCare Rehabilitation. Ex. 7 at 7-9. When her condition did not notably improve after nine sessions, her therapy was suspended on May 16, 2017, pending further evaluation by a doctor. *Id.* at 36.

On June 6, 2017, Ms. Kraus presented orthopedic surgeon Dr. George Russell Huffman, who diagnosed Petitioner with right shoulder bursitis. Ex. 8 at 1-3. Ms. Kraus reported having “had pain at the time of vaccination and within two days, the pain escalated and increased to the point that she could not sleep at night, could not use her arm for activities of daily living.” *Id.* at 2. Dr. Huffman recommended a second steroid injection in her right shoulder, which Ms. Kraus received roughly two months later, on August 15, 2017. *Id.* at 2-4. By October 3, 2017, however, Ms. Kraus exhibited good range of motion and minimal signs of impingement. Ex. 8 at 6. Dr. Huffman prescribed Voltaren gel and advised that she return in three months. *Id.*

A year later, on October 4, 2018, Ms. Kraus was seen at Bucks Family Medicine, P.C. by Dr. David E. Lewis for “ongoing right arm/shoulder pain.” Ex. 13 at 1. Dr. Lewis noted that Ms. Kraus “had previously followed with Ortho who recommended [follow up] in 1/2018 but she was not able to go. She is now doing more lifting as a result of her job.

This increased lifting is worsening the shoulder pain with radiation into her arm (these are what the symptoms had been).” *Id.* The physical examination showed decreased right shoulder range of motion, and assessments included “Pain in right shoulder” and “incomplete rotator cuff tear or rupture of right shoulder.” *Id.* at 2. Ms. Kraus later saw Dr. Huffman, on November 20, 2018, for “SIRVA reaction to a flu vaccination into her deltoid on 09/26/2016. She continues to have pain and discomfort.” Ex. 12 at 1. Physical examination showed “pain around the deltoid tuberosity...positive Jobe’s and very mild impingement.” *Id.*

On April 12, 2019, Ms. Kraus was seen at Penn Orthopaedic Institute by Dr. Huffman for a follow up on her right shoulder. Ex. 12 at 4. The record from this visit reflects the following:

[Petitioner] had a SIRVA reaction to a flu vaccination in the right delta on 09/26/2016. She had a course of physical therapy early on, but said that her shoulder was too painful for the therapy to have been effective. She points to the range from the lateral aspect of the acromion down to the deltoid tuberosity for the preponderance of her pain. She rates her pain as 3/10 today.

Id. The plan was to for Ms. Kraus to resume physical therapy, and “[i]f she is still struggling, a bursectomy decompression may be warranted.” *Id.* at 4.

Ms. Kraus completed 11 physical therapy sessions at NovaCare Rehabilitation, from May 9, until June 27, 2019. Ex. 16. She returned to Dr. Huffman, on July 16, 2019, for a follow up on her right shoulder pain. Ex. 15 at 1. Dr. Huffman noted Petitioner “had a SIRVA reaction to a flu vaccination in the right deltoid on 09/26/2016...I did give her a corticosteroid injection at one point that helped. She has done physical therapy, which helped to a point but now has continued pain. Now, her pain is not in the shoulder as much, which feels good.” *Id.* Petitioner was instructed to continue using Voltaren Gel to “break the cycle of inflammation in [the deltoid] region,” and to return as needed. *Id.*

No additional medical records have been filed. However, Ms. Kraus filed two affidavits and three witness affidavits, which include her husband, Cliff Kraus, her daughter, Kristin Kraus, and a work colleague, Catherine Barbagallo. Exs. 17-20. Each of these witnesses describe conversations or personal recollections to help substantiate Ms. Kraus claims of shoulder pain within the 48-hour period after her vaccination.

III. Parties' Arguments

Ms. Kraus requests that I issue a ruling determining that: (1) she experienced the onset her right shoulder pain within 48 hours of receiving the flu vaccine on September 26, 2016, and (2) she has otherwise established entitlement to compensation for her SIRVA injury. Petitioner's Motion for Ruling on the Record ("Mot.") at 1-2, ECF No. 47.

Respondent argues that Petitioner has failed to satisfy the criteria for a Table SIRVA because she "has failed to provide preponderant evidence that her right shoulder pain began within 48 hours of vaccine administration." Respondent's Brief ("Opp.") at 6 (citing 42 C.F.R. § 100.3(a)(XIV)(B) (Table entry for SIRVA following the influenza vaccine) and (c)(10) (additional criteria for SIRVA set forth in the QAI)). Respondent maintains that the medical records are unclear as to when Petitioner's right shoulder pain began, and therefore, criterion (ii) under the QAI for SIRVA has not been met. Opp. at 6-7, ECF No. 54.

Ms. Kraus filed a Reply reiterating that the medical records and witness affidavits all support a finding that her shoulder pain began within 48 hours of vaccination and she is therefore entitled to compensation. Petitioner's Reply to Motion for Ruling on the Record ("Reply") at 4-5, ECF No 55. The parties' positions and evidence are considered below.

IV. Fact Findings and Ruling on Entitlement

a. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a

petitioner may present testimony which is “consistent, clear, cogent, and compelling.” *Sanchez v. Sec’y of Health & Human Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner’s injury, and the lack of other award or settlement,⁵ a petitioner must establish that he suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged

⁵ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for his injury. See § 11(c)(1)(A)(B)(D)(E).

signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

If, however, petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, he must prove that the administered vaccine caused injury to receive Program compensation. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). The Federal Circuit has held that to establish an off-Table injury, petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing

of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Id.* at 1280.

A. Factual Findings Regarding QAI Criteria for Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

1. Prior Condition

The first requirement under the QAIs for a Table SIRVA is a lack of a history revealing problems associated with the affected shoulder which were experienced prior to vaccination and would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Although Respondent noted that the December 20, 2016 medical record from Dr. Borgia notes that Ms. Kraus had a fall that may have affected her right shoulder 15 years prior, Respondent has not formally contested that Petitioner meets this criterion. I also have found no evidence in the records that Ms. Kraus had any evidence of a right shoulder injury in the years prior to her September 16, 2016 vaccination. I therefore find that Ms. Kraus has satisfied the first SIRVA requirement.

2. Onset of Pain

In order to meet the definition of a Table SIRVA, a petitioner must show that she experienced the first symptom or onset (here, pain) within 48 hours of vaccination (42 C.F.R. §§ 100.3(a)(XIV)(B)) and 100.3(c)(10)(ii) (QAI criteria)).

Respondent argues that Ms. Kraus did not report her shoulder pain to a medical provider until nearly three months after her vaccination, and in the interim, made no mention of such pain when she saw Dr. Mathew concerning a chronic ankle problem. Opp. at 6. Respondent also notes that at Ms. Kraus's initial visit to Dr. Borgia, she complained of "right shoulder pain x years" that had "become more painful" in the past month, and referenced a fall Ms. Kraus had 15 years prior. *Id.* Respondent states that the physical exam was "poorly described" but no abnormal findings were noted. Dr. Borgia later amended her note to relate Ms. Kraus's shoulder pain to her vaccine, rather than a past fall. Respondent further cites to a number of notations in the record where Ms. Kraus states that her pain began two days "after vaccination," which Respondent interprets to

mean outside the Table time period of 48 hours. Notably, however, Respondent also cites to the records where Ms. Kraus reports that her shoulder pain began “within two days”. Opp at 7. Respondent thus claims these references make it “unclear” when Petitioner’s shoulder pain began – meaning that Table onset cannot be demonstrated.

Respondent has reasonably raised questions about the extent to which this record establishes Table onset. In particular, the amended statements in Dr. Borgia’s records are grounds for concern (although the fact that the record was amended not long after the visit, and many months prior to the case’s initiation, diminishes my concerns somewhat). Nevertheless, the overall record permits the conclusion that onset “more likely than not” occurred within 48 hours of vaccination.

First, Respondent unpersuasively maintains that the various instances in the medical records where Ms. Kraus reported that her shoulder pain began two days “after” vaccination do not make the onset of her shoulder pain unclear. In fact, my interpretation of these statements is exactly the opposite of what Respondents wants me to infer.

Presumably, an individual seeking medical treatment is unaware of the 48-hour onset requirement for shoulder pain to satisfy the SIRVA QAI when he or she is presenting to a medical provider to be treated for shoulder pain. As a result, an approximation of “two days” after vaccination is reasonable, if imprecise, evidence that shoulder pain began in the day or two after vaccination – especially when (as here) it is coupled with statements that *do* put the onset of her shoulder pain squarely within the 48 hour onset window. See e.g., Ex. 8 at 2 (June 6, 2017 note by Dr. Huffman states “pain began within a day or two after an influenza vaccination.”); Ex. 4 at 15 (Dr. Borgia’s note states “flu shot in her right arm and ever since then she has had pain in her upper arm that goes up to her shoulder.”); Ex. 5 at 3 (Dr. Todd notes “has rt (right) delt [deltoid] /shoulder pain since receiving flu shot on 9-26-16”); Ex. 6 at 7 (Orthopedist Steven Caruso noted that petitioner had right shoulder pain beginning in September since receiving “a flu shot and she states that she has had this pain since this flu shot”); Ex. 7 at 34 (Physical therapist Brendan Cummings noted “shoulder pain that began in late September after patient received flu shot.”); Ex. 8 at 2 (Orthopedist G. Russell Huffman noted “pain began within a day or two after an influenza vaccination and within two days, the pain escalated and increased to the point that she could not sleep at night”); Ex. 16 at 1 (Petitioner presented to NovaCare Rehabilitation for an evaluation and it was noted, “Presents with s/o pain in R shoulder after receiving flu vaccine 2016”). The totality of this evidence is favorable to Petitioner despite the presence of some record instances that are more vague or imprecise.

Second, I am not persuaded by Respondent’s argument that because Ms. Kraus did not complain to her podiatrist, Dr. Mathew, on October 17, 2016, about her shoulder

pain, she must not have been experiencing shoulder pain at that time. As Petitioner notes in her brief, it is entirely understandable why Ms. Kraus would not have reported her *shoulder* pain to a *podiatrist*, whom she sought for evaluation of left foot and ankle pain. There is no reason for her to have informed a specialist of all of her concurrent or comorbid issues that that time.

Third, delay in treatment in this case does not preclude a finding of Table onset. As I have previously explained in other SIRVA onset rulings, it is common for petitioners to delay seeking treatment, thinking the injury will resolve on its own, since patients are often told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. Indeed, Ms. Kraus confirmed in her affidavit that she expected to have some shoulder pain immediately after receiving her vaccination. Ex. 9 at 1, ¶1; Ex. 17 at 1, ¶2. Thus, I find the length of time Ms. Kraus waited before contacting her physician's office to report her shoulder pain to be entirely reasonable in these circumstances.

Finally, I note that proof of onset need not come from records created within the relevant onset period – as Respondent often seems to assume. The Vaccine Act clearly does not require that symptoms be recorded within a specific timeframe to be preponderantly established. Rather, it requires only that onset *occurs* in the relevant timeframe. Section 13(b)(2). In this case, there are medical records created in a generally-contemporaneous time to the reporting of shoulder pain⁶ that clearly relate onset of Petitioner's shoulder pain to the 48-hour time period after vaccination. While evidence of post-vaccination pain from a record created no more than two days post-vaccination would constitute particularly strong evidence of onset, it is not the only form of persuasive evidence to establish onset.

Based upon the above, I find there is preponderant evidence which establishes the onset of Ms. Kraus's right shoulder pain was more likely than not within 48-hours of vaccination.

3. Scope of Pain and Limited ROM

I likewise find that the scope of pain and limited range of motion was limited to Petitioner's right shoulder. To establish a Table SIRVA, a petitioner's pain and reduced

⁶ As the Federal Circuit has noted, it is appropriate for a special master to give greater weight to evidence contained in medical records created closer in time to the vaccination, even if the information is provided as part of a medical history. *Cucuras*, 993 F.2d at 1528 (medical records are generally trustworthy evidence).

ROM must be limited to the shoulder in which the vaccination alleged as causal was administered. 42 C.F.R. § 100.3(c)(10)(iii).

Ms. Kraus was diagnosed and treated solely for pain and limited range of motion to her right shoulder and Respondent does not contest that Petitioner fails to meet this criterion. I therefore find that there is preponderant evidence to support a finding that Petitioner's pain and reduced range of motion was limited to her right shoulder. Thus, she satisfies the third criterion for a SIRVA injury.

4. Other Condition or Abnormality

The last QAI criterion for a Table SIRVA states that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent has likewise not contested that Petitioner meets this criterion and I have found no evidence in the record of any other condition or abnormality that would explain Ms. Kraus's right shoulder pain and symptomology.

Thus, the record contains preponderant evidence establishing that there is no other condition or abnormality which would explain the symptoms of Petitioner's right shoulder injury.

A. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received the flu vaccine intramuscularly in her right shoulder on September 26, 2016. Ex. 1 at 1; Ex. 2 at 46; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for her injury. Petition at 2; Section 11(c)(1)(E) (lack of prior civil award).

As stated above, I have found that the onset of Petitioner's right shoulder pain was within 48 hours of vaccination. See 42 C.F.R. § 100.3(c)(10)(ii) (setting forth this QAI requirement). This finding also satisfies the requirement that Petitioner's first symptom or manifestation of onset occur within the time frame listed on the Vaccine Injury Table. 42

C.F.R. § 100.3(a)(XIV)(B) (listing a time frame of 48 hours for a Table SIRVA following receipt of the influenza vaccine).

The next criteria which must be satisfied by Petitioner involves the duration of her SIRVA. For compensation to be awarded, the Vaccine Act requires that a petitioner suffer the residual effects of her shoulder injury for more than six months. See Section 11(c)(1)(D)(i) (statutory six-month requirement). The records demonstrate, and Respondent does not contest, that Ms. Kraus suffered the residual effects of her shoulder injury for more than six months. See, e.g., Ex. 12 at 4; Ex. 15 at 1, Ex. 16. Thus, this requirement is also met.

In view of the evidence of record, I find that Petitioner is entitled to compensation.

V. Conclusion

For all of the reasons discussed above and based on consideration of the record as a whole, **I find that Petitioner's right shoulder injury meets the definition for a Table SIRVA. Thus, causation is presumed, and Petitioner is entitled to compensation in this case. A separate damages order will be issued.**

IT IS SO ORDERED.

s/ Brian H. Corcoran

Brian H. Corcoran
Chief Special Master